



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0261; FRL-9339 -6]

Ametoctradin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ametoctradin in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010- 0261. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory

Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shaunta Hill, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8961; e-mail address: *hill.shaunta@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding

the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0261 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0261, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 19, 2010 (75 FR 28009) (FRL-8823-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7695) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide ametoctradin, including its metabolites and degradates, in or on brassica, head and stem, subgroup 5A at 12 parts per million (ppm); brassica, leafy greens, subgroup 5B at 50 ppm; grape at 5.0 ppm; grape, raisin at 8 ppm; hop, dried cones at 9 ppm; onion, bulb, subgroup 3-07A at 1.2 ppm; onion, green, subgroup 3-07B at 16 ppm; vegetable, cucurbit, group 9 at 4.5 ppm; vegetable, fruiting, group 8-10 at 2 ppm; vegetable, leafy, except brassica, group 4, at 70 ppm, and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm. That notice referenced

a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has proposed different tolerance levels under a cooperative global review process. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ametoctradin including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with ametoctradin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In toxicity testing with ametoctradin, no single dose or repeated dose study performed by any route of exposure produced a significant toxic effect up to or within 75-80% of the limit dose (1000 mg/kg/day). This includes the studies performed with the ametoctradin metabolites. There was also no evidence of carcinogenicity or mutagenicity and therefore ametoctradin is considered “Not Likely to Be Carcinogenic to Humans”.

Specific information on the studies received and the nature of the adverse effects caused by ametoctradin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “BAS 650 F (Ametoctradin): Human Health Risk Assessment for the Proposed New Fungicide Active Ingredient,” at p. 10 in docket ID number EPA-HQ-OPP-2010-0261.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below

which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>. Based on the available data, there were no adverse acute or chronic effects identified as to any population groups (including infants and children).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ametoctradin, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from ametoctradin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects

were identified in the toxicological studies for ametoctradin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* No chronic dietary exposure assessment was conducted because no chronic effect of concern was identified in the available data.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that ametoctradin does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* Exposure to ametoctradin via drinking water from the proposed uses is expected to be minimal based on its short half life in soil. Ametoctradin degradates (F01, F02, F03, F04) are likely to contribute much greater drinking water exposure because they are more persistent and more mobile than the parent. However, no adverse effects were observed in the submitted toxicological studies for ametoctradin regardless of the route of exposure. Thus, no drinking water exposure assessments are needed.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ametoctradin is not registered for homeowner uses; however, some of the proposed uses could be used by commercial applicators in areas that residential postapplication exposure could occur (i.e., ornamentals on golf courses or in residential landscapes). No adverse effects were observed in the submitted toxicological studies for ametoctradin regardless of the route of exposure. Thus, no residential handler or postapplication exposure assessments are needed.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found ametoctradin to share a common mechanism of toxicity with any other substances, and ametoctradin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ametoctradin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Based on the complete database, there were no adverse effects noted in the developmental toxicity or reproductive toxicity studies.

3. *Conclusion.* Based on review of the available ametoctradin toxicological studies, no toxicological points of departure were selected for ametoctradin and thus, an additional safety factor to protect children is not needed. That decision is based on the following findings:

- i. The toxicity database for ametoctradin is complete.
- ii. There is no indication that ametoctradin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that ametoctradin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no concerns identified with regard to exposure to ametoctradin and thus there are no uncertainties identified in the exposure databases.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse

effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, ametoctradin is not expected to pose an acute risk.

2. *Chronic risk.* No adverse effect resulting from a chronic exposure was identified and no chronic endpoint was selected. Therefore, ametoctradin is not expected to pose a chronic risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, ametoctradin is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, ametoctradin is not expected to pose a intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, ametoctradin is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to ametoctradin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology using liquid chromatography tandem mass spectrometry (LC/MS/MS) is available to enforce the tolerance expression. The method

may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for ametoctradin.

C. Revisions to Petitioned-For Tolerances

Ametoctradin is a candidate for global registration in the USA, Australia, and Canada and import tolerance establishment in the European Union (EU) for varying uses. Under a cooperative joint review process, harmonized MRLs were proposed by the Agency, the Pesticide Management Regulatory Agency of Canada (PMRA), and the EU.

Although much effort was made to harmonize with the EU proposed import-MRLs, there remained a few crops (celery, broccoli, cucumber and hops) where the proposed global registration recommended MRLs differed. This is primarily because EU's practice for setting MRLs is to lower the MRL as much as possible hence they try

to assign MRLs to selected individual crops within a crop group as opposed to assigning a crop group MRL which is normally higher than all the estimated MRLs for individual crops. This approach is impractical for North American Free Trade Agreement (NAFTA) regions as there are other crops within a crop group petitioned for registration.

The Organization for Economic Co-operation and Development's (OECD) MRL calculation procedures used to estimate the proposed MRLs. The MRLs were derived using the average of individual residue data points from each field trial conducted at maximum applications rates and the lowest PHI, and assuming the presence of adjuvants (as indicated on the proposed labels). In estimating MRLs for crop groups, the highest estimated MRL for individual representative crops were selected.

For some crops, field trials were conducted at concentrated and diluted solutions. In these cases, MRLs were chosen using only the residue data for applications with concentrated solution if the concentrated solution residue data showed significant differences from the whole residue dataset (concentrated and diluted solution applications).

V. Conclusion

Therefore, tolerances are established for residues of ametoctradin, including its metabolites and degradates, in or on brassica, head and stem, subgroup 5A at 9.0 ppm; brassica, leafy greens, subgroup 5B at 50 ppm; grape at 4.0 ppm; grape, raisin at 8.0 ppm; hop, dried cones at 10 ppm; onion, bulb, subgroup 3-07A at 1.5 ppm; onion, green, subgroup 3-07B at 20 ppm; spinach at 50 ppm; vegetable, cucurbit, group 9 at 3.0 ppm; vegetable, fruiting, group 8-10 at 1.5 ppm; vegetable, leafy, except brassica, group 4, except spinach at 40 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.05 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 27, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.663 to read as follows:

§ 180.663 Ametoctradin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide ametoctradin, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only ametoctradin (5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine).

Commodity	Parts per million
Brassica, head and stem, subgroup 5A	9.0
Brassica, leafy greens, subgroup 5B	50
Grape	4.0
Grape, raisin	8.0
Hop, dried cones	10.0
Onion, bulb, subgroup 3-07A	1.5
Onion, green, subgroup 3-07B	20.0
Spinach	50.0
Vegetable, cucurbit, group 9	3.0

Vegetable, fruiting, group 8-10	1.5
Vegetable, leafy, except <i>Brassica</i> , group 4, except spinach	40.0
Vegetable, tuberous and corm, subgroup 1C	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012-10950 Filed 05/08/2012 at 8:45 am; Publication Date: 05/09/2012]